

Notice of Allowability

Application No.

09/836,035

Examiner

Evelyn Huang

Applicant(s)

CHEN ET AL.

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1625

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address--

All claims being allowable, PROSECUTION ON THE MERITS IS (OR REMAINS) CLOSED in this application. If not included herewith (or previously mailed), a Notice of Allowance (PTOL-85) or other appropriate communication will be mailed in due course. **THIS NOTICE OF ALLOWABILITY IS NOT A GRANT OF PATENT RIGHTS.** This application is subject to withdrawal from issue at the initiative of the Office or upon petition by the applicant. See 37 CFR 1.313 and MPEP 1308.

1. ☒ This communication is responsive to 9-13-2004.
2. ☒ The allowed claim(s) is/are 1-29 and 31.
3. ☐ The drawings filed on _____ are accepted by the Examiner.
4. ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
 - a) ☐ All b) ☐ Some* c) ☐ None of the:
 1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this national stage application from the International Bureau (PCT Rule 17.2(a)).

* Certified copies not received: _____.

Applicant has THREE MONTHS FROM THE "MAILING DATE" of this communication to file a reply complying with the requirements noted below. Failure to timely comply will result in ABANDONMENT of this application.

THIS THREE-MONTH PERIOD IS NOT EXTENDABLE.

5. ☐ A SUBSTITUTE OATH OR DECLARATION must be submitted. Note the attached EXAMINER'S AMENDMENT or NOTICE OF INFORMAL PATENT APPLICATION (PTO-152) which gives reason(s) why the oath or declaration is deficient.
6. ☐ CORRECTED DRAWINGS (as "replacement sheets") must be submitted.
 - (a) ☐ including changes required by the Notice of Draftsperson's Patent Drawing Review (PTO-948) attached
 - 1) ☐ hereto or 2) ☐ to Paper No./Mail Date _____.
 - (b) ☐ including changes required by the attached Examiner's Amendment / Comment or in the Office action of Paper No./Mail Date _____.

Identifying indicia such as the application number (see 37 CFR 1.84(c)) should be written on the drawings in the front (not the back) of each sheet. Replacement sheet(s) should be labeled as such in the header according to 37 CFR 1.121(d).
7. ☐ DEPOSIT OF and/or INFORMATION about the deposit of BIOLOGICAL MATERIAL must be submitted. Note the attached Examiner's comment regarding REQUIREMENT FOR THE DEPOSIT OF BIOLOGICAL MATERIAL.

Attachment(s)

1. ☐ Notice of References Cited (PTO-892)
2. ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3. ☐ Information Disclosure Statements (PTO-1449 or PTO/SB/08), Paper No./Mail Date _____
4. ☐ Examiner's Comment Regarding Requirement for Deposit of Biological Material
5. ☐ Notice of Informal Patent Application (PTO-152)
6. ☒ Interview Summary (PTO-413), Paper No./Mail Date _____
7. ☒ Examiner's Amendment/Comment
8. ☒ Examiner's Statement of Reasons for Allowance
9. ☐ Other _____

EXAMINER'S AMENDMENT

1. An examiner's amendment to the record appears below. Should the changes and/or additions be unacceptable to applicant, an amendment may be filed as provided by 37 CFR 1.312. To ensure consideration of such an amendment, it MUST be submitted no later than the payment of the issue fee.

Authorization for this examiner's amendment was given in a telephone interview with Mr. Bernstein on 9-24-2004. The examiner suggested amending claim 1 by deleting 'the prodrug thereof' and specifying the compound of formula I as 'isolated' compound to set a demarcation from the known [5-cyclopropyl-1-(quinolin-5-yl)-1H-pyrazole-4-carbonyl]guanidine precursor compound. Support for 'isolated' compound is found on page 9, line 17 of the specification.

The application has been amended as follows:

- a. Claim 1,
 - Replace 'A compound' with – An isolated compound --.
 - Delete 'a prodrug thereof'.
 - Delete 'or of said prodrug with the proviso that rejection over Hamanaka (WO 99/4366) is not included'.
- b. Claim 2,
 - Before '[5-cyclopropyl-1-(2-quinolon-5-yl)-1H-pyrazole-4-carbonyl]guanidine', insert – Isolated --.
 - Delete 'or a pharmaceutically acceptable salt thereof'.
- c. Claim 3,
 - Line 3, delete 'a prodrug thereof'.
 - Line 4, delete 'or of said prodrug'.
- d. Claim 5,
 - Line 2, delete 'a prodrug thereof'.
 - Line 3, delete 'or of said prodrug'.
- e. Claim 26,

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- Replace 'an amount of the' with --a --.
 - Line 2, delete 'a prodrug thereof'.
 - Line 3, delete 'or of said prodrug'.
- f. Claim 27,
- Line 3, delete 'a prodrug thereof'.
 - Line 4, delete 'or of said prodrug'.

REASONS FOR ALLOWANCE

2. The following is an examiner's statement of reasons for allowance:

Claims 1-29, 31 are allowed.

The 102(a) rejection over Hamanaka (WO 99/43663) is withdrawn upon reconsideration in view of the amendment deleting the 'prodrug thereof' and specifying that the compound of formula I as 'an isolated' compound, thereby setting a demarcation from the metabolite of the parent drug compound in a physiological situation.

The 103 rejection over Hamanaka (WO 99/43663) and the 103 rejection over Hamanaka (WO 99/43663) in view of Munson and Beedham, and the corresponding obviousness type double patenting rejections over US Patent No. 6492401, are withdrawn upon reconsideration in view of the amendment and Applicant's remarks. While Hamanaka has generically discloses the instant, a 2-hydroxyquinoline species compound has not been shown. Modifying the 5-cyclopropyl-1-(quinolin-5-yl)-1H-pyrazole-4-carbonyl]guanidine of Hamanaka by adding a hydroxy at the 2-position to arrive at the instant is not readily apparent to one of ordinary skill in the art. In re Baird, 29 USPQ2d, 1550.

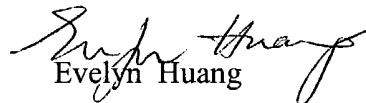
3. Any comments considered necessary by applicant must be submitted no later than the payment of the issue fee and, to avoid processing delays, should preferably accompany the issue fee. Such submissions should be clearly labeled "Comments on Statement of Reasons for Allowance."

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4. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Evelyn Huang whose telephone number is 571-272-0686. The examiner can normally be reached on Tuesday-Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).



Evelyn Huang

Primary Examiner

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